



September 17, 2021

On September 13, 2021, [HHS issued a 9th Amendment to its PREP Act Declaration](#) to authorize pharmacists to order and administer COVID-19 therapeutics and for qualified pharmacy technicians and interns to administer COVID-19 therapeutics.

As of August 10, 2021, REGEN-COV has Emergency Use Authorization (EUA) to be administered for the treatment of mild to moderate COVID-19 in non-hospitalized patients with high risk factors for progression of disease as well as for post-exposure prophylaxis for COVID-19 in high-risk patients who are not fully vaccinated or who are not expected to mount an adequate immune response to completed SARS-CoV-2 vaccination. Further, REGEN-COV has been authorized for administration via intravenous infusion or subcutaneous injection.

The HHS amendment authorizes pharmacists to order and administer COVID-19 therapeutics that have been approved or authorized by the FDA and that are administered orally, intramuscularly, or subcutaneously. The amendment also authorizes qualified pharmacy technicians and interns to administer COVID-19 therapeutics.

Individuals who will be administering COVID-19 therapeutics must maintain current certification in CPR and complete an ACPE-approved practical training program which includes:

- Hands-on injection technique,
- Clinical evaluation of indications and contraindications of COVID-19 therapeutics,
- Recognition and treatment of emergency reactions to COVID-19 therapeutics, and
- Any other training required by the FDA.

A supervising pharmacist must be readily and immediately available to a qualified pharmacy technician who is administering COVID-19 therapeutics.

Pursuant to [Iowa Code section 155A.46](#), subsection 2, a pharmacy must maintain records of the order/administration of COVID-19 therapeutics and provide notification to the patient's primary care provider following administration of the therapeutic.

Following administration of COVID-19 therapeutics, the following reporting is REQUIRED:

- To the patient's primary care provider (pursuant to Iowa Code section 155A.46, subsection 2) and
- To [HHS TeleTracking COVID-19 Portal](#)

**A pharmacy which intends to order and administer COVID-19 therapeutics (pursuant to the PREP Act or a board-approved statewide protocol, if available) must update its pharmacy license online profile (link [HERE](#)) to indicate "Yes" to the pharmacy service "Statewide Protocol - COVID-19 Test and Treat" (understanding that the provision of this service may be under the HHS PREP Act authority at this time).

On Monday, September 13, 2021, HHS modified the distribution process for monoclonal antibodies (mAbs), including REGEN-COV, which provides for state-level allocation and distribution. Pharmacies that wish to be approved as a mAb provider must complete the [IDPH COVID-19 Monoclonal Antibody Provider Request Form](#). Pharmacies should be aware that current demand for mAbs far exceeds supply and that new provider requests and allocation of product may be delayed.

Additional resources:

[Fact Sheet for Health Care Providers - EUA for REGEN-COV](#)

[FDA Letter of Authorization for REGEN-COV](#)

[NIH COVID-19 Treatment Guidelines](#)

[REGEN-COV Subcutaneous Injection Instructions for Healthcare Providers](#)